ISRCTN18301880 https://doi.org/10.1186/ISRCTN18301880

Bioavailability of a ColoPulse tablet

Submission date 16/12/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/12/2014	**Overall study status** Completed	
Last Edited 16/07/2015	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study will test whether the amount of active substance released from a new tablet (ColoPulse tablet) differs in patients with Crohn's disease compared with healthy volunteers. The influence of food and the time when food is eaten after administration of the tablets will also be investigated. In the healthy volunteers the pH of their gastro-intestinal tract will be investigated with a measuring capsule (IntelliCap).

Who can participate?
Patients (age 18-65) with Crohn's disease in remission and healthy volunteers (age 18-65) with no gastrointestinal surgery can participate in this study.

What does the study involve?
All participants will have the same tests. They come to the study facility for 2 test-days with at least one week in between. On the test day two tablets are administered simultaneously and breakfast is taken either 1 hour or 3 hours later, depending on the test day. On the second test day the healthy volunteers will also receive the IntelliCap. Data will be collected by a small recorder worn around the waist until excretion of the IntelliCap. For all subjects urine and breath samples will be taken up to 24 hours after taking the tablets. At 5.00 p.m. subjects are allowed to go home. They will take breath and urine samples themselves during the evening and next morning.

What are the possible benefits and risks of participating?
The participants have no direct benefits from participating in this study. No side effects are to be expected.

Where is the study run from?
University Medical Center Groningen, the Netherlands.

When is the study starting and how long is it expected to run for?
Recruitment for this study started in 2010 and was finished in April 2011. The study was performed in March and April 2011.

Who is funding the study?
This study was funded by the University Medical Center Groningen, the Netherlands. IntelliCaps were provided by Medimetrics, the Netherlands.

Who is the main contact?
Marina Maurer (hospital pharmacist)
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-013471-21

Protocol serial number
N/A

Study information

Scientific Title
BIOavailability of a COloPulse tablet in healthy volunteers and Crohn's patients; influence of gastro-intestinal pH, food and time of food intake

Acronym
BIOCOP-2

Study objectives
In a collaboration of UMCG and RUG a technology has been developed that allows selective delivery of drugs in the terminal ileum/proximal colon (ColoPulse technology, pH-based) after oral intake of a tablet or capsule. The ColoPulse technology has been tested in healthy volunteers. However, before a patient study with active substances can be started, it must be validated that the release profile of the formulation used is correct in the aimed population. This is the purpose of the BIOCOP-2 bioavailability study. In order to obtain additional information about the functioning of the pH-sensitive coating of the 'modified-release' tablet, the gastro-

intestinal pH-profile of healthy volunteers will be determined with the help of the determined IntelliCap®.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics boards of the University Medical Center Groningen, 19/11/2010, ref: 2009.188

Study design
Prospective bioavailability study (cross-over) in healthy volunteers and Crohn's patients

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Release of a ColoPulse tablet in healthy volunteers and patients with Crohn's disease (in remission)

Interventions
Period 1: an oral dose of 50 mg 15N2-ureum immediate release tablet in combination with an oral dose of 50 mg 13C-ureum modified-release tablet at Day 1 in a fasted condition. Non-standardized breakfast after 1 h. Period 2: an oral dose of 50 mg 15N2-ureum immediate release tablet in combination with an oral dose of 50 mg 13C-ureum modified-release tablet at Day 1 in a fasted condition. Standardized breakfast after 3 h. Furthermore, the gastro-intestinal pH-profile of the healthy volunteer will be measured at test day 2 using the IntelliCap.

Intervention Type
Device

Primary outcome(s)
1. Local bioavailability in healthy volunteers and patients with Crohn's disease.
2. Time between intake and response in healthy volunteers and patients with Crohn's disease. This is the cumPDR 5%: (lagtime) at the time when release exceeds 5% of the maximum cumPDR (13 C-urea).
3. Pulse time in healthy volunteers and patients with Crohn's disease. This is the difference between times at which the maximum PDR is reached and the lagtime.
4. Description of the gastro-intestinal pH profile of healthy volunteers.

Key secondary outcome(s))
Investigate influence of food and time of food intake on functioning of a ColoPulse dosage form

Completion date
20/04/2011

Eligibility

Key inclusion criteria
1. Healthy adults (18-65 years) able to sign informed consent
2. No medication use during the last 3 months that can influence the gastrointestinal flora (e.g., antibiotics)
3. No medication use during the last 4 weeks of drugs that may affect the gastrointestinal transit time (e.g., laxatives, antacids)
4. No use of NSAIDs during the last 4 weeks

Patients
1. Adults (18-65 years) able to sign informed consent with Crohn's disease (in remission Harvey Bradshaw index ≤3) (18-65)
2. No medication use during the last 3 months of drugs that may affect the gastrointestinal flora (e.g., antibiotics)
3. No medication use of drugs that may affect the gastrointestinal pH (e.g., antacids)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
Healthy volunteers
1. With known gastro-intestinal disorders such as ulcerative colitis, Crohn's disease, spastic colon, colon cancer, ileus, ostomy, gastric and/or intestinal infection
2. Gastrointestinal operation (except appendix operation)
3. Presence Helicobacter pylori

Patients
1. Crohn's disease is in the active stage (Harvey Bradshaw ≥ 4)
2. Presence Helicobacter p ylori

Date of first enrolment
25/01/2011

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
HPC EB70
Hanzeplein 1
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Sponsor information

Organisation
University Medical Center Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Other

Funder Name
Invesitigator initiated and funded

Funder Name
IntelliCap systems were provided by Medimetrics Personalized Drug Delivery BV Eindhoven (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/12/2013		Yes	No
Results article	results	15/07/2015		Yes	No